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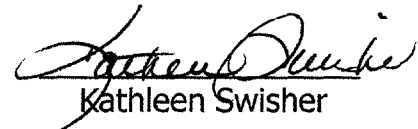
Date: March 15, 2004

From: Acting Director, Regulations and Policy Staff (HFM-17), CBER

Subject: Docket No. 1980N-0208, Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review; Final Rule and Final Order.

To: Jennie Butler, Division of Dockets Management (HFA-305)

Please add the enclosed documents to Docket No. 1980N-0208, Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review; Final Rule and Final Order. An index for the documents is also enclosed. Thank you.


Kathleen Swisher

1980 N-0208

REF 1

Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review; Final Rule and Final Order [Docket No. 1980N-0208]

1. February 13, 1973 (38 FR 4319); "Procedures for Review of Safety, Effectiveness and Labeling;" Biological Products.
2. November 20, 1973 (38 FR 32048 at 32052); Biological Products General, "Reorganization and Republication."
3. June 19, 1974 (39 FR 21176); Certain Biological Products, "Request for Data and Information Regarding Safety, Effectiveness, and Labeling Review."
4. November 21, 1980 (45 FR 77135);
 - a. Bacterial Vaccines and Toxoids; Blood and Blood Derivatives; Availability of Final Reports of Advisory Review Panels.
 - b. Panel Report.
5. Notifiable Diseases - Summary of reported cases, United States, Historical Tables – 1943-1992
6. October 5, 1982 (47 FR 44062); Licensing; Reclassification Procedures To Determine That Licensed Biological Products Are Safe, Effective, and Not Misbranded Under Prescribed, Recommended or Suggested Conditions of Use.
7. May 15, 2000 (65 FR 31003); Biological Products; Bacterial Vaccines and Related Biological Products; Implementation of Efficacy Review; Proposed Order.
8. May 29, 2001 (66 FR 29148); Biological Products; Bacterial Vaccines and Related Biological Products; Revocation of Biologics Licenses.
9. Docket # 01P-0471
 - a. Citizen Petition dated October 12, 2001, submitted by Russell E. Dingle.
 - b. FDA's response dated August 28, 2002, inclusive of three attachments.
10. Pittman, P.R., et al., "Anthrax vaccine: immunogenicity and safety of a dose-reduction, route-change comparison study in humans," *Vaccine*, 20:1412-1420, 2002.
11. *Berlex Laboratories, Inc. v. FDA*, 942 F. Supp. 19 (D.D.C. 1996).
12. 61 FR 40153 (August 1, 1996); Revocation of Certain Regulations; Biological Products.